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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,845	01/17/2002	Jesse M. Carter		2089

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Jesse M. Carter
P.O. Box 13275
Tampa, FL 33681

EXAMINER	
GAKH, YELENA G	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 07/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,845	CARTER ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

EXAMINER'S AMENDMENT

1. The examiner amends the claims for the purpose of facilitating prosecution of the Application and placing the amended claims in compliance with new patent rules.

Claims are amended as follows:

Claim 1 (Currently Amended) An automated method for detecting the presence of ~~oxidants~~ adulterants in a urine sample comprising:

a) placing an aliquot of the urine in a first automated analyzer sample cup;

b) placing a standard of known concentration of ~~oxidants~~ any one of bleach, chromate, iodic acid, iodates, and peroxides in a second automated analyzer sample cup;

c) placing the cups in a sample tray within the automated analyzer, transferring the urine from the first sample cup and the standard from the second sample cup to discrete cuvettes mounted within the automated analyzer, injecting an aqueous reagent composition comprising an acid at 0.01 N concentration or higher and one or more phenylamine chromogenic indicators from the group consisting of N,N, ~~N, N~~, N',N' -tetramethyl-1,4-phenylenediamine, N,N-diethyl-1,4,-phenylenediamine, 2,3,5,6-tetramethyl-1,4-phenylenediamine, N,N-dimethyl-p-phenylenediamine, 2,4,6-trimethyl-1,3-phenylenediamine, N,N, ~~N, N~~, N',N' -tetramethylbenzidine, 3,3,5,5-tetramethyl-benzidine, N,N, ~~N, N~~, N',N' -tetramethyl-4,4-diaminestilbene and O-tolidine into cuvettes and mixing;

d) determining the sample-reagent mixture's absorbance with the automated analyzer's spectrophotometer at a preprogrammed wavelength between 400 and 700 nm at a preprogrammed time between 12 seconds and 600 seconds after the phenylamine chromogenic indicator is added to the cuvettes; and

e) comparing the absorbance of the urine-reagent mixture to the absorbance of the standard-reagent mixture and thereby determining if the sample has an abnormal amount of ~~oxidant compound~~ adulterants consisting of bleach, chromate, iodic acid, iodates, or peroxide present.

Claim 2 (Currently Amended) An automated method for detecting the presence of

~~oxidants~~ bleach, chromate, iodic acid, iodates, and peroxide in a urine sample comprising:

a) placing an aliquot of the urine in a first automated analyzer sample cup;

b) placing a standard of known concentration of ~~oxidant~~ adulterant in a second automated analyzer sample cup;

c) placing the cups in a sample tray within the automated analyzer, transferring the urine from the first sample cup and the standard from the second sample cup to discrete cuvettes mounted within the automated analyzer, injecting a first aqueous reagent composition comprising potassium iodide and one or more buffering compounds into the cuvettes;

d) injecting a second aqueous reagent composition comprising an acid at 0.01 N concentration or higher and one or more phenylamine chromogenic indicators from the group consisting of N,N, ~~N, N~~, N',N'-tetramethyl-1,4-phenylenediamine, N,N-diethyl-1,4,-phenylenediamine, 2,3,5,6-tetramethyl-1,4-phenylenediamine, N,N-dimethyl-p-phenylenediamine, 2,4,6-trimethyl-1,3-phenylenediamine, N,N, ~~N, N~~, N',N'-tetramethylbenzidine, 3,3,5,5-tetramethylbenzidine, N,N, ~~N, N~~, N',N'-tetramethyl-4,4-diaminestilbene and O-tolidine into the cuvettes and mixing; ~~and~~

e) determining the sample-reagent mixture's absorbance with the automated analyzer's spectrophotometer at a preprogrammed wavelength between 400 and 700 nm at a preprogrammed time between 12 seconds and 600 seconds after the phenylamine chromogenic indicator is added to the cuvettes; and

f) comparing the absorbance of the urine-reagent mixture to the absorbance of the standard-reagent mixture and thereby determining if the sample has an abnormal amount of ~~oxidant compound~~ bleach, chromate, iodic acid, iodates, or peroxide present.

Claim 3 (Currently Amended) The process according to claim 1 wherein the phenylamine chromogenic indicators include one or more of the following group:
N,N, ~~N, N~~, N',N'-tetramethyl-1,4-phenylenediamine, N,N-diethyl-1,4,-phenylenediamine, 2,3,5,6-tetramethyl-1,4-phenylenediamine, N,N-dimethyl-p-phenylenediamine, 2,4,6-trimethyl-1,3-phenylenediamine, N,N, ~~N, N~~, N',N'-tetramethylbenzidine, 3,3,5,5-tetramethylbenzidine, N,N, ~~N, N~~, N',N'-tetramethyl-4,4-diaminestilbene and O-tolidine.

Claim 4 (Original) The process according to claim 1 wherein the acid is a mineral acid from

the following group: hydrochloric acid, phosphoric acid, sulfuric acid, glacial acetic acid, and perchloric acid.

Claim 5 (Currently Amended) The process according to claim 1 wherein the indicator is N,N, ~~N, N~~, N',N' - tetramethylbenzidine in 0.25 N hydrochloric acid and the wavelength is 415, and the read time is 60 seconds.

Claim 6 (Currently Amended) The process according to claim 2 wherein the phenylamine chromogenic indicators include one or more of the following group:
N,N, ~~N, N~~, N',N' -tetramethyl-1,4-phenylenediamine, N-N-diethyl-1,4,-phenylene-diamine, 2,3,5,6-tetramethyl-1,4-phenylenediamine, N,N-dimethyl-p-phenylenediamine, 2,4,6-trimethyl-1,3-phenylenediamine, N,N, ~~N, N~~, N',N' -tetramethylbenzidine, 3,3,5,5-tetramethylbenzidine, N,N, ~~N, N~~, N',N' -tetramethyl-4,4-diaminestilbene and O-tolidine.

Claim 7 (Original) The process according to claim 2 wherein the acid is a mineral acid from the following group: hydrochloric acid, phosphoric acid, sulfuric acid, glacial acetic acid, and perchloric acid.

Claim 8 (Original) The process according to claim 2 wherein sodium iodide is substituted for potassium iodide.

Claim 9 (Original) The process according to claim 2 wherein buffers include sodium hydroxide, sodium acetate, aminomethyl propanol, barbitol, borate, bicine, bis-tris-propane, carbonate, CAPS, Glycine, MOPSO, phosphate, POPSO, TABS, and TRIS.

Claim 10 (Currently Amended) The process according to claim 2 wherein the first aqueous reagent composition consists of potassium iodide, sodium acetate, and sodium hydroxide and the second aqueous reagent composition consists of N,N-diethyl-1,4-phenylenediamine sulfate, N,N, ~~N, N~~, N',N' -tetramethyl-1,4-phenylenediamine and hydrochloric acid.

2. In response to the Applicant's amendment and remarks the examiner withdraws the rejections

and establishes new grounds for rejections.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 recite "an acid at 0.01 N concentration or higher". It is not clear, if the acid should be organic or inorganic, or it does not matter. The concentration definition as "0.01 N or higher" is indefinite, as it is not clear, how high the concentration might be, since it is not limited at the upper level.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. **Claims 1-4 and 6-10** are rejected under 35 U.S.C. 102(e) as being anticipated by Novinski et al. (US 6,861,262B2).

Novinski teaches an automated method for detecting the presence of at least one oxidizing agent including those recited in claim 1 by spectrophotometric detection of the absorbance of a mixture of an urine sample with a reagent comprising N,N-diethylphenylene

diamine, acid, creatinine and iodide at wavelength between 470 and 604 nm and comparing the result with a calibration curve to calculate the concentration of the adulterant (see Claims).

7. **Claim 5** is rejected under 35 U.S.C. 102(e) as being anticipated by Anne et al. (US 2002/0160439 A1).

Anne teaches a method for colometric detecting the presence of at least one oxidizing agent including those recited in claim 1 by mixing an urine sample with a reagent comprising tetramethylbenzidine, acid and a buffer, and comparing the result with a standard calibration.

Response to Arguments

8. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

6/27/05

YELENA GAKH
PRIMARY EXAMINER